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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,241	04/07/2004	Steve Koh	A04P1034	9568

36802 7590 06/06/2006

PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER

TOTH, KAREN E

ART UNIT	PAPER NUMBER
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3735

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/821,241

Applicant(s)

KOH, STEVE

Examiner

Karen E. Toth

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 10-22 is/are rejected.
- 7) ☒ Claim(s) 5-9 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>04/07/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3, 10-12, 17-19, 21 are rejected under 35 U.S.C. 102(a) as being anticipated by Cho'542 (US Patent 6641542).

Regarding Claim 1, Cho'542 discloses a method for monitoring apnea comprising monitoring blood pressure (column 6, lines 52-55) and detecting non-obstructive apnea (column 1, lines 33-48) based on changes in blood pressure (column 5, lines 26-34).

Regarding Claim 3, Cho'542 further discloses that the blood pressure sensors may be implantable (column 3, lines 14-16).

Regarding Claim 10, Cho'542 further discloses delivering apnea therapy in response to its detection (column 3, lines 13-23).

Regarding Claim 11, Cho'542 further discloses delivering overdrive pacing therapy to the patient's heart (column 10, lines 5-7).

Regarding Claim 12, Cho'542 further discloses delivering dynamic atrial overdrive pacing therapy to the patient (column 10, lines 5-7 and 14-16).

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Regarding Claim 17, Cho'542 further discloses recording diagnostic information representative of apnea detection (column 8, lines 39-45).

Regarding Claim 18, Cho'542 discloses a system comprising a blood pressure detector (element 540), and a blood pressure-based non-obstructive apnea detector (column 5, lines 26-40).

Regarding Claim 19, Cho'542 discloses a system comprising a blood pressure detector (element 540); a blood pressure-based non-obstructive apnea detector (column 5, lines 26-40); and an apnea treatment system that operates in response to apnea detection (column 10, lines 1-5).

Regarding Claim 21, Cho'542 further discloses that the apnea treatment system may include an overdrive pacing system for delivering overdrive pacing to the patient's heart (column 10, lines 5-7 and 14-16).

Regarding Claim 22, Cho'542 discloses a system comprising means for detecting blood pressure (elements 210 and 540; column 4, lines 51-62), means for tracking changes in blood pressure (column 4, lines 62-66)

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 2, 4, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cho'542 in view of Kunig'917 (US Patent 6520917).

Regarding Claim 2, Cho'542 discloses all the elements of the current invention, as applied to Claim 1 above, except for the step of monitoring blood pressure being performed to monitor diastolic pressure.

Kunig'917 teaches a method of monitoring apnea comprising monitoring diastolic blood pressure (column 6, lines 1-11), in order to accurately diagnose episodes of apnea.

It would have been obvious to one of ordinary skill in the art at time the invention was made to have made the method of Cho'542 with the step of monitoring diastolic blood pressure, as taught by Kunig'917, in order to accurately diagnose episodes of apnea.

Regarding Claim 4, Cho'542 discloses all the elements of the current invention, as applied to Claim 1 above, except for tracking changes in blood pressure from beat to beat, identifying a period of time having a substantial

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decrease in blood pressure, and associating that period with non-obstructive apnea.

Kunig'917 teaches a method of monitoring apnea comprising tracking changes in blood pressure from beat to beat, identifying a period of time having a substantial decrease in blood pressure, and associating that time period with non-obstructive apnea (column 6, lines 1-15; Figure 4).

Regarding Claim 22, Cho'542 discloses a system comprising means for detecting blood pressure (elements 210 and 540; column 4, lines 51-62), means for tracking changes in blood pressure (column 4, lines 62-66). Cho'542 does not disclose means for identifying a period of time having a substantially decreased blood pressure and means for associating non-obstructive apnea with the period of decreased blood pressure.

Kunig'917 teaches a system comprising means for identifying a period of time having a substantially decreased blood pressure (column 1, line 65 to column 2, line 6; and column 6, lines 6-10); and means for associating apnea with the decreased pressure period (figure 4; column 6, lines 5-15), in order to properly diagnose episodes of apnea.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Cho'542 with means for identifying periods of decreased blood pressure and means for associating apnea with said periods, as taught by Kunig'917, in order to properly diagnose episodes of apnea.

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5. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cho'542 in view of Birnbaum'575 (US Patent 4580575).

Regarding Claim 15, Cho'542 discloses all the elements of the current invention, as applied to Claim 1 above, except for generating a warning signal in response to apnea in order to alert the patient.

Birnbaum'575 teaches a method for monitoring apnea comprising generating an alarm to alert the patient when apnea is detected (column 9, lines 4-9), so that the patient restarts breathing.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Cho'542 with the step of generating an alarm to alert the patient when apnea is detected, as taught by Birnbaum'575, so that the patient will restart breathing.

Regarding Claim 16, Cho'542 in view of Birnbaum'575 discloses all the elements of the current invention, as applied to Claim 15 above, except for the warning signal generation including at least one of transmitting a signal to an external alarm device, electrically stimulating selected muscles of the patient with an implantable electrical stimulator to cause the muscles to twitch, or causing an implantable vibration device to vibrate.

Birnbaum'575 further teaches that the patient is alerted by a signal sent to an external device (column 9, lines 4-9), so that the patient is made aware of the respiratory issue.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Cho'542 in view of

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Birnbaum'575, and alerted the patient by sending a signal to an external device, as taught by Birnbaum'575, so that the patient is made aware of the respiratory issue.

6. Claims 14 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cho'542 in view of Stahmann'561 (US Patent Application Publication 2005/0115561).

Regarding Claim 14, Cho'542 discloses all the elements of the current invention, as applied to Claims 1 and 10 above, except for the method being used in a system having an implantable phrenic nerve stimulator and comprising a step for delivery of diaphragmatic pacing to the phrenic nerves.

Stahmann'561 teaches a method of apnea monitoring comprising delivery of apnea treatment using implanted stimulators to stimulate phrenic nerves (paragraphs [1041] and [1197]), in order to restart the patient's breathing.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Cho'542, and added the step of delivering apnea therapy via implantable phrenic nerve stimulation, as taught by Stahmann'561, in order to restart the patient's breathing.

Regarding Claim 20, Cho'542 discloses all the elements of the current invention, as applied to Claim 19 above, except for the system comprising a diaphragmatic pacing system for delivering diaphragmatic pacing.

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Stahmann'561 teaches an apnea treatment system comprising a diaphragmatic pacing system for delivering diaphragmatic pacing (paragraphs [1041] and [1197]), in order to restart a patient's breathing.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Cho'542 with the diaphragmatic pacing system of Stahmann'561, in order to restart a patient's breathing.

Allowable Subject Matter

7. Claims 5-9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to anticipate or make obvious the method of Claims 5-7, including, *inter-alia*, the specific steps of evaluating the blood pressure at a plurality of beats, calculating the change in blood pressure between beats, calculating the change in the change in blood pressure, identifying times when the change is negative and the change in the change is less than a threshold value, and using the results to determine the onset of apnea.

The prior art of record fails to anticipate or make obvious the method of Claims 8-9, including, *inter-alia*, the monitoring blood pressure only when monitoring respiratory movement shows substantially no motion.

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Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 6881192 to Park, which discloses a system and method for detecting and treating apnea.


9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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ROBERT L. NASSER
PRIMARY EXAMINER